

Attorney Docket No.: 4409.214-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Jonassen et al.

Confirmation No.: 2082

Application No.: 09/772,607

Group Art Unit: 1656

Filed: January 30, 2001

Examiner: Kam, Chih Min

Confirmation No: 2082

For: Protracted Polypeptides

PETITION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Patentee hereby requests reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 145 to 329 days, is respectfully requested.

REMARKS

Measuring Overlap of "A Delay" and "B Delay"

"A Delays" are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in Wyeth et al. v. Jon W. Dudas (580 F.Supp.2d 138, 88 U.S.P.Q.2d 1538, D.D.C. 2008), the only way that these periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. Id.

The PTA for the instant patent application as provided in the USPTO's PAIR system and the PTA calculation submitted with the Notice of Allowance, apparently relies on the premise that the application was delayed under 35 U.S.C. § 154(b)(1)(B) *before* the initial three-year period expired. The Wyeth v. Dudas court determined that this construction cannot be squared with the language of 35 U.S.C. § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." "B delay" begins only after the PTO has failed to issue a patent within three years, not before. Id.

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

"A Delay"

I. USPTO Delay

1.) An Office Action following a reply was due on or before January 10, 2002 (the date that is 4 months after the date on which the reply was filed). In this regard, Applicants filed a response on September 10, 2001, but did not receive an Office Action until May 31, 2002, thereby according a USPTO delay of 141 days.

2.) An Office Action following a reply was due on or before April 9, 2003 (the date that is 4 months after the date on which the reply was filed). In this regard, Applicants filed a response on December 9, 2002, but did not receive an Office Action until July 1, 2003, thereby according a USPTO delay of 83 days.

3.) An Office Action following a reply was due on or before May 2, 2004 (the date that is 4 months after the date on which the reply was filed). In this regard, Applicants filed a response on January 2, 2004, but did not receive an Office Action until June 15, 2004, thereby according a USPTO delay of 44 days. However, these days overlap with "B Delay."

II. Applicant Delay

Pursuant to MPEP § 2733, and in furtherance with the practitioner's duty of candor and good faith practice before the Office, Applicant believes the USPTO miscalculated the Applicant delay. A response to Notice to Comply with Requirements for Sequence Disclosures mailed September 28, 2001 was due on or before December 28, 2001 (the date that is 3 months after the date on which the

Notice was issued). The submitted response was not compliant and Supplemental Notices to Comply were sent to Applicant on February 8, 2002 and March 6, 2003. The Notice to Comply was satisfied on April 3, 2003. In addition, an Office Action was mailed May 31, 2002 such that a reply following an Office Action was due on or before August 31, 2002 (the date that is 3 months after the date on which the Office Action was issued). In this regard, Applicants filed a response on December 9, 2002. Due to overlap, this accords a total Applicant delay of 460 days.

“B Delay”

The present application was filed January 30, 2001, which is a Continuation of U.S. Application Number 09/068,822, filed May 14, 1998, which is a National Phase Application of PCT/DK96/00106, filed March 18, 1996.

The period beginning on January 31, 2004 (the day after the date that is three years after January 30, 2001), and ending December 21, 2006 (the date which the first RCE was filed), is 1055 days in length.

In view of the period of “B Delay” detailed above, the total “B Delay” for this patent should be calculated as 1055 days. The PTO calculated 748 days of delay for issuance of a patent more than three years after filing. Patentee respectfully submits that the PTO’s calculation of this “B Delay” is incorrect and that the correct PTO Delay for issuance beyond three years from filing is 1055 days. See 37 C.F.R. §§ 1.702(b) and 1.703(b).

Sum of “A Delay” and “B Delay”

As detailed above, “A Delay” accumulated during the following period:

January 10, 2002 to May 31, 2002 = 141 days;

April 9, 2003 to July 1, 2003 = 83 days; and

May 2, 2004 to June 15, 2004 = 44 days (which overlaps “B Delay”).

As detailed above, “B Delay” accumulated during the following period:

January 31, 2004 to December 21, 2006 = 1055 days.

Accordingly, the sum of 268 days “A Delay,” and 1055 days “B Delay,” is 1323 days.

Overlap of "A Delay" and "B Delay"

As noted above, there is an overlap of "A Delay" and "B Delay." Accordingly, 44 days of "A Delay" + "B Delay" need to be subtracted from the sum."

Applicant Delay

Total Applicant Delay calculated as set forth in 37 C.F.R. § 1.704 accumulated during the following periods:

December 28, 2001 to April 3, 2003 = 460 days,

October 1, 2003 to January 2, 2004 = 93 days,

September 15, 2004 to December 15, 2004 = 91 days,

June 29, 2005 to September 29, 2005 = 92 days,

March 1, 2006 to June 1, 2006 = 92 days,

June 14, 2007 to August 14, 2007 = 61 days, and

August 8, 2008 to October 8, 2008 = 61 days.

Accordingly, Total Applicant Delay is calculated as 950 days.

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

In consideration of the events described above, Applicants believe the PTA calculation of 145 days is incorrect. As such, Applicants respectfully request reconsideration of the PTA in the following manner:

- 1) Total PTO Delay should be calculated as 1323 days (*i.e.*, the sum of 268 days of "A Delay" and 1055 days of "B Delay");
- 2) Overlap of "A Delay" and "B Delay" is 44 days;
- 2) Total Applicant Delay should be calculated as 950 days; and
- 3) Total PTA should be calculated as 329 days.

Please apply the fee of \$200 required under 37 C.F.R. § 1.1 8(e) and any other required charges or credits to Deposit Account No. 14-1447, referencing Attorney Docket Number 4409.214-US.

Respectfully submitted,

Date: May 18, 2010

/Richard W. Bork, Reg. No. 36,459/

Richard W. Bork, Reg. No. 36,459

Novo Nordisk Inc.

Customer Number 23650

(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650

PATENT TRADEMARK OFFICE